

THE CAMBRIDGE STATISTICS DISCUSSION GROUP

Wednesday 10th December 2003 7:15 for 7:45

Hopkinson Room,
University of Cambridge Computer Laboratory,
Pembroke Street, Cambridge

Active Control, Noninferiority and Equivalence in Clinical Trials

Brian Wiens

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Abstract: Studies of new pharmacological therapies require demonstrating that the new therapy is efficacious—that is, superior to receiving no treatment. When an existing therapy is available, it is often considered unethical to withhold active treatment from any study subject. Therefore efficacy must be inferred indirectly, usually by comparing the investigational treatment to an existing treatment that has previously been shown superior to placebo (no treatment). In this talk we introduce statistical theory supporting analysis of such studies. Neyman-Pearson theory carries over directly, but the role of randomization in supporting inference may not. Other issues such as multiple comparisons carry over, if one is careful with the details.

Speaker: Brian Wiens is Senior Manager at Amgen Inc. in Thousand Oaks, California, USA, a biotechnology company, working on clinical trials in the oncology therapeutic area. Prior to joining Amgen in 2000, he worked at Merck Research Labs in Philadelphia and at Hoechst Marion Roussel and Quintiles, both in Kansas City. Brian completed his doctorate in the Statistics Department of Temple University in Philadelphia under Prof. Boris Iglewicz. He completed prior degrees at Colorado State University and at Tabor College. Current research interests include design and analysis of active control trials and multiple comparison issues.

Directions: Enter the New Museums site through the arch from Pembroke Street. Turn to the left in front of the building with the brown iron staircase and pass through the passage way by the tree. Enter the lobby which is straight in front of you and find the back entrance to the Computing Service on your left. When inside follow the signs to the Hopkinson Room. It is not possible to park on the New Museums site in the evening. The back entrance to the Computing Service will be locked at 7:45. Arrivals after 7:45 can gain admittance by contacting the secretary on 07761769436.

Provisional Next Meetings:

3rd February – Angela Wood (MRC Biostatistics) on 'Dealing with Missing Outcome Data'.

3rd March – Haidee Philpott & John Law (NIAB) on 'A case study in Winter Wheat Fungicide Trials in the UK 1991-2001'.

5th April – Anthony Edwards (Gonville and Caius).

13th May – Melanie Cooray (Statwood Partnership).

Supper: Some members eat before a talk at the University Centre meeting in the downstairs bar at 6pm. All welcome !

Subscriptions: of 4 pounds per member are now due for the 2003-2004 session.

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